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(71) Applicant *(for all designated States except US)*: PROSTALUND OPERATIONS AB [SE/SE]; Höstbruksvägen 14, S-226 60 Lund (SE).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: BOLMSJÖ, Magnus [SE/SE]; Karlavägen 14, S-223 40 Lund (SE).

(74) Agent: HANSSON THYRESSON PATENTBYRÅ AB; Patent Dept., Box 73, S-201 20 Malmö (SE).

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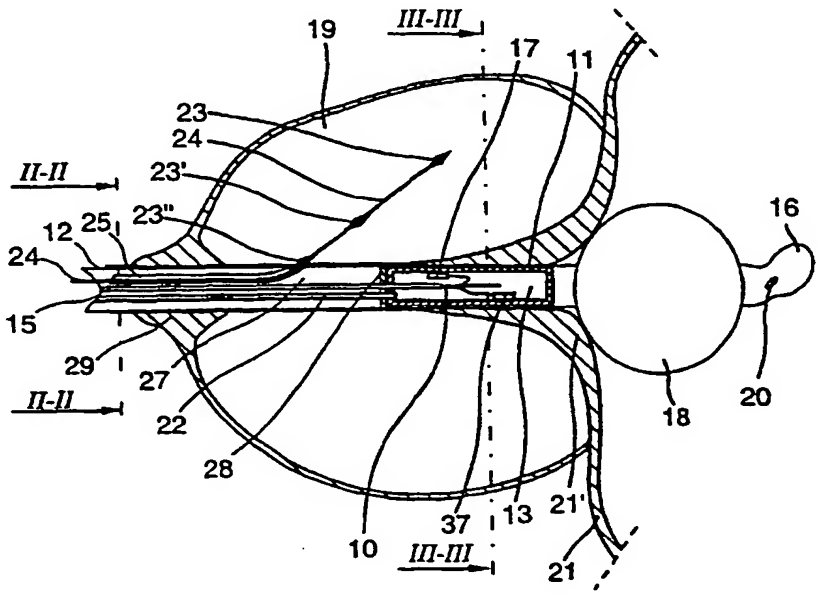
(54) Title: METHOD AND DEVICE FOR HEAT TREATMENT OF BODY TISSUE



(57) Abstract

A device for heat treatment of prostate, comprising a treatment catheter (12) with a fluid reservoir (11) and heating means (10) which is arranged within the treatment catheter (12) and emits electromagnetic radiation for heating of the surrounding bodily tissue. The fluid reservoir (11) constitutes an integrated part of the catheter for treatment and is positioned in the catheter so that, when inserted in a patient, it extends to cover the area heated by the heating means (10) between the prostatic apex and bladder neck (21'). The fluid reservoir (11) also constitues a closed chamber which is connectable via a channel (22) passing through the catheter (12) for treatment. A stop (28) for the heat-absorbing means is embodied distal to said heating means (10) and distal to said heat reservoir (11).

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METHOD AND DEVICE FOR HEAT TREATMENT OF BODY TISSUE

TECHNICAL FIELD OF THE INVENTION

The invention concerns a device for heat treatment of bodily tissue according to patent claim 1.

Heat treatment yields good treatment results with certain types of disease conditions involving unnatural growth of tissue. The tissue is heated to the extent that it dies. Examples of such disease conditions are certain types of cancer and benign prostate hyperplasia, BPH. During treatment certain portions of the tissue are heated so that tissue death ensues, while other portions of tissue must or should be protected. The temperature in the area of treatment should be at least 50°C. Duration of treatment is typically 1 hour but can be shorter. The disease conditions that are primarily indicated are those which occur in tissue surrounding cavities in the body, for example the prostatic gland.

STATE OF THE ART

Different devices can be used in order to induce heating. Devices for heating by means of laser as well as with microwaves and radio frequencies are common. A technique is known through US-A-5, 257,977, according to which a catheter is provided with a reservoir for fluid. The reservoir is flexible and is connected via channels through the catheter with a heating device located outside the body. A fluid is heated in a heating device and circulated through the channels and the reservoir. The rise of temperature in the reservoir brings about heating of the surrounding tissue.

Since the channels pass through tissue that should not be treated, they must be heat insulated. According to US-A-5, 257,977 the heat insulation is brought about by means of a space filled with gas that surrounds the channels. The function of the heat insulation is very important, for which rea-

son great care and considerable expense must be devoted to this part of the treatment catheter.

A more highly developed catheter for treatment is shown and described in WO 97/02794, according to which a heating device is contained inside an expandable reservoir. The heating device is provided with energy from an assembly outside of the body for heating of fluid inside the reservoir. Some of the disadvantages involving undesirable heating of certain tissue are avoided in this manner. The heating device is designed according to WO 97/02794 as a resistance wire or similar and heats the fluid through convection. The heat transferred from the fluid to the surrounding tissue gives locally good results. A disadvantage is that the effect in the tissue at a farther distance from the reservoir is insignificant.

Heat-treating with a treatment catheter that is equipped with a microwave antenna is also known with the mentioned course of disease. Examples of such microwave treatment are known previously through US-A-5480417 and US-A-5234004. Characteristic for previously known microwave treatment is that the prostate tissue is heated with microwaves. The intention is to heat parts of the prostate gland so that the tissue coagulates, i.e. dies. The element that emits the microwave radiation consists of a coaxial cable with an antenna at its end that is included in a catheter for treatment. Cooling fluid circulates through the catheter. The intention with the cooling is to protect the prostatic urethra, that is to say the part of the urethra that runs through the prostate gland from being affected and damaged by the heat that is generated by the microwaves. Another reason for cooling the catheter is to transport away waste heat in the coaxial cable.

It has long been viewed as important to protect the part of urethra that passes through the prostate – the prostatic urethra - during microwave treatment of benign prostate enlargement. This protection of the prostatic urethra hinders the treatment from being really effective, however, since parts of the obstructing tissue closest to the urethra are not heated but remain unaffected because of the cooling. The clinical result of heat treatment is dependent on the amount of tissue that coagulates. The degree of coagu-

lation depends in turn on temperature in combination with the length of treatment. The temperature in turn depends on the input of energy and the carrying away of heat by the blood flow. If cooling of the prostatic urethra is done for the purpose of protecting it from being destroyed, the loss of heat energy from the area of treatment is increased, which is counterproductive and severely diminishes the effectiveness of the treatment.

There are also designs with completely uncooled treatment catheters (US patent US4967765). In such embodiments the microwave energy must, however, be limited so that the urethra and penis are not heated due to cable losses in the coaxial cable that conducts the microwaves to the antenna. Because of this restriction, completely uncooled catheters are not preferred, since the microwave power that can then be used (max 30 Watt) is so low that one cannot achieve the high tissue temperature that is needed in order for the coagulation of tissue to occur to the desired extent.

THE INVENTION IN SUMMARY

A purpose of the invention is to increase the effectiveness of treatment with a treatment catheter of previously known technology. The higher treatment effectiveness means shorter treatment times. Alternatively, less microwave power can be used, which increases safety for the patient. These objectives are achieved by incorporation of the special features described in patent claim 1.

The effectiveness of treatment is increased in that a treatment catheter designed for microwave treatment of the prostate contains a fluid reservoir filled with non-circulating fluid that surrounds the microwave antenna between the prostatic apex and the bladder neck and thus prevents the prostatic urethra from being cooled during treatment. The fluid reservoir is heated partly by losses in the antenna device itself that are converted to Joule heat and partly by direct absorption of microwave energy in the fluid itself. The absence of cooling of the prostatic urethra means that less microwave energy can be used to achieve the desired intra-prostatic temperature

or alternatively that the treatment time can be shortened. Both possibilities are advantageous for the patient in that they increase safety for the patient and diminish the risk of damage caused by the treatment as a result of high total power output.

Further advantages and special features of the invention emerge from the following description, drawings, and dependent patent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail with the aid of examples of embodiments with reference to the attached drawings on which:

FIG 1 is a principal cross-sectional view in the longitudinal direction of an embodiment of a treatment catheter according to the invention.

FIG 2 is a transverse sectional view of the treatment catheter from line *II-II* in FIG 1,

FIG 3 is a transverse view of the treatment catheter from line *III-III* in FIG 1

FIG 4 shows a schematic connection of a treatment catheter to external devices according to one embodiment of the invention.

THE INVENTION

In the embodiment of a treatment catheter 12 according to the invention as shown in FIG 1 a reservoir 11 isolated from the catheter cooling is positioned in the part of the catheter that is surrounded by the prostate gland. The treatment catheter is in the first place intended for treatment of prostate tissue. Before treatment reservoir 11 is filled via a channel 22 in the treatment catheter 12 with fluid 13, for example sterile water or cooking salt solution. Fluid 13 in the reservoir constitutes a dielectric that improves the adjustment between the microwave antenna and the prostate tissue.

A heating device 10 is provided inside treatment catheter 12 for heating tissue surrounding treatment catheter 12. Heating device 10 emits elec-

tromagnetic radiation, preferably in the form of microwaves. Heating device 10 suitably includes a microwave antenna. The energy emitted from heating device 10 is absorbed to a small degree by the fluid in reservoir 11 but the overwhelming part of the energy is radiated out and absorbed in the surrounding tissue. Energy is supplied via a feed cable 15 from an energy supply unit 14. (See FIG 4.) In a preferred embodiment first heating device 10 includes an antenna that can be designed, for example, as a monopole antenna, dipole antenna, or a helix antenna. The antenna is covered by a protective sheath 40 up to its radiating section in order to lessen radiation from other sections.

Treatment catheter 12 according to FIG 1 is introduced through the urethra so that tip 16 extends into urinary bladder 21. A bladder or balloon 18 connected to the treatment catheter is expanded inside urinary bladder 21 and prevents unintended withdrawal of the treatment catheter during the process of treatment. The active part of the treatment catheter is thus centrally located in the tissue that is to be treated, in this case in prostate 19 distal to bladder neck 21'. The treatment catheter 12 is flexible and pliable in order to be introduced flexibly through the urethra to the treatment position.

In the treatment catheter fluid channel 26 that ends in balloon 18 is also present (see FIG 2 and 3). Through it fluid can be supplied for expansion of balloon 18 when the treatment catheter is brought into the desired position for treatment. Fluid channel 26 is also used in order to empty balloon 18 after treatment is completed and before the treatment catheter is withdrawn from the urethra. A conventional hypodermic needle or similar is suitably used for the filling and emptying of balloon 18.

Feed cable 15, through which energy is conducted to first heating device 10, is heated as a result of losses. In order to avoid thermally induced damage to tissue outside the area of treatment, for example on sphincter muscle 29 that surrounds the urethra outside of the prostate or to the penis, feed cable 15 is cooled. This is accomplished by providing cooling channels 27 in treatment catheter 12, preferably around feed cable 15. (See also FIG

2 and FIG 3.) Cooling channels 27 are embodied according to the invention with a delimiter or stop 28, at which cooling fluid circulating in cooling channels 27 return. In this way cooling of heating device 10 itself and of reservoir 11 is avoided, which in turn means that the energy that needs to be conducted from unit 14 can be diminished. With lower levels of energy, the risk of maltreatment and damage to healthy tissue also diminishes.

Temperature sensors 23, 23', and 23" are arranged on carrier 24 in order to be able to track the temperature development during heat treatment. Carrier 24 can be extended through a channel or tube 25, which runs through the treatment catheter. Carrier 24 or temperature sensor 23 is suitably embodied with, or as, a tip that can penetrate in part a membrane or wall in the treatment catheter and in part the bodily tissue. Tube 25 is embodied so that carrier 24 with temperature sensors 23 is extended out of the treatment catheter at a suitable angle and can be driven out to a suitably radial distance from the treatment catheter.

Heating of tissue thus occurs partly through heating of the fluid contained in reservoir 11 that emits heat directly via heat conduction to adjacent tissue (i.e., the prostatic urethra) and partly through electromagnetic radiation. The total treatment area is thus larger than with conventional heating, where the prostatic urethra is cooled and thus not destroyed during treatment.

Fluid 13 in the reservoir is heated by interaction with microwave antenna 10 to a temperature such that surrounding tissue, i.e., the prostatic urethra, is coagulated. Since the highest temperature is reached in the tissue closest to reservoir 11, the prostatic urethra will to a large degree be affected and therewith be damaged and die. This part of the urethra is, however, regenerated relatively quickly. A special temperature sensor 37 is suitably located in reservoir 11 for continuous measurement of the temperature of fluid 13 in reservoir 11.

A resulting heat profile, i.e. a curve that shows tissue temperature radially outward from the centre of the treatment catheter, is accordingly differ-

ent from the profile that can be achieved with conventional technology employing a completely cooled catheter or a lack of cooling entirely.

When treatment is finished, the energy supply to heating device 10 is interrupted and reservoir 11 can be emptied of fluid by suction via channel 22. It is not suitable to remove the treatment catheter as long as the reservoir has a temperature such that damage may occur with passage of the reservoir through the body. When catheter 12 is introduced into the urethra with a tip into urine bladder 21, drainage of urine and any other fluid from the urine bladder can occur through a drainage channel provided in catheter 12. The drainage channel runs through the whole catheter 12 and ends with an opening 20 near the tip of catheter 12. With certain types of treatment it can be suitable to leave catheter 12 in place during a certain period of time after the treatment. The function of the drainage channel during this time is also to drain the urine bladder.

As soon as urine passes again through the urethra in the prostate, the treated and dead tissue will be eliminated with the urine. A remaining hollow space in the prostate after the tissue was removed assures the passage of urine in the correct manner. The process of healing including elimination of coagulated tissue can continue for some months.

FIG 2 schematically shows an embodiment of a treatment catheter 12. Treatment catheter 12 is designed with a number of cavities and channels extending along the treatment catheter. Feed cable 15 runs through a central cavity 30, which is preferably well shielded. Cooling fluid is transported in separated cooling channels 27, preferably in a circulating system. In a first cooling channel 27 a tube 25 for carrier 24 is arranged. In a similar manner fluid channel 26 for balloon 18 and channel 22 for fluid reservoir 11 are arranged in other cooling channels 27. A drainage channel, which ends in opening 20 in the treatment catheter, can be arranged in a similar way in a cooling channel.

The cross section view in FIG 3 shows an example of how reservoir 11 can be embodied. Essentially the whole internal volume of treatment catheter 12 is occupied by reservoir 11. Partition walls are indicated and can be

used, for example, in order to control feed cable 15 and fluid channel 26 for balloon 18. Reservoir 11 can alternatively consist of connected channel elements that constitute a continuation of cooling channels 27 after stop 28.

The block diagram in FIG 4 schematically shows the various function blocks that can be included in a treatment assembly with a treatment catheter according to the invention. As indicated above, energy is supplied to heating device 10 from energy supply unit 14. A central control unit 32 is operatively connected with energy supply unit 14 and a display unit 33 and with a pumping and cooling device 34 and a fluid supply device 35. Control unit 32 is additionally operatively connected to an input device, for example, in form of a keyboard 36. Control unit 32, keyboard 36, and display unit 33 can also be included in a conventional computer with a monitor and keyboard.

Control unit 32 is operatively connected to temperature sensors 23 and 37 and can control energy supply unit 14 dependent on the current temperature in the area of treatment so that suitable power is supplied to heating device 10. In this manner it is possible to increase the temperature considerably with good safety in fluid reservoir 11 and thus in surrounding tissue so that tissue death occurs in the desired way. Data on temperature from temperature sensors 23 and 37 can also be shown continuously on display unit 33.

Pumping and cooling device 34 is connected to cooling channels 27 and pumps suitable cooling fluid through cooling channels 27 in order primarily to cool feed cable 15 while it is being extended forward to heating device 10. Fluid supply device 35 is used when fluid reservoir 11 is to be filled and emptied. Control unit 32 can monitor the pumping and filling.

A preferred embodiment according to the invention also includes a pressure meter 17 that is operatively connected to reservoir 11 in order to monitor the pressure in the reservoir. Pressure meter 17 is also operatively connected to central control unit 32 so that the pressure in fluid reservoir 11 will affect the process of treatment. The pressure is changed depending on

how the treatment proceeds. For reasons of safety the treatment should be interrupted if the pressure in fluid reservoir 11 falls abruptly, for example as a result of the failure of a partition in reservoir 11. In a corresponding way, treatment should be interrupted if the temperature in reservoir 11 becomes so high that the fluid in it boils.

Feed cable 15 can be embodied in the form of a coaxial cable with a protective sheath and an inner conductor. The sheath also constitutes an outer conductor. The inner conductor acts as an antenna beyond the end of the sheath.

PATENT CLAIMS

1. A device for heat treatment of prostate, comprising a treatment catheter (12) with a fluid reservoir (11) and first heating means (10) which is arranged within the treatment catheter (12) and emits electromagnetic radiation for heating of the surrounding bodily tissue, *characterised in*

that said fluid reservoir (11) constitutes an integrated part of the catheter for treatment and is positioned in the catheter so that, when inserted in a patient, it extends to cover the area heated by the heating means between the prostatic apex and bladder neck (21').

that the fluid reservoir (11) constitutes a closed chamber wich is connectable via a channel (22) passing through the catheter (12) for treatment,

that a feed cable (15) intended for the heating means (10) is thermally connected to the heat-absorbing means (27) and is cooled up to the wall but not any further.

that a stop (28) for the heat-absorbing means is embodied distal to said heating means (10) and distal to said heat reservoir (11).

2. A device according to Claim 1, wherein said stop (28) with the treatment catheter (12) in its treatment position is located proximal to a sphincter (29) surrounding urethra.

3. A device according to Claim 1, wherein said stop (28) with the treatment catheter (12) in its treatment position is located proximal to the prostatic apex.

4. A device according to Claim 1, wherein said heating means (10) comprises a microwave antenna.

5. A device according to Claim 1, wherein said heat-absorbing means (27) is

designed as cooling channels that run in the catheter (12) for treatment.

6. A device according to Claim 5, wherein said stop (28) is a partition closing the cooling channels (27).

7. A method for heat treatment of prostate by electromagnetic radiation, wherein a treatment catheter (12) with a fluid reservoir (11) and a heating means (10) arranged within the treatment catheter (12) and emitting electromagnetic radiation for heating of the surrounding bodily tissue is inserted through urethra to a treatment location in the prostate, *c h a r a c t e r i s e d by*

emitting electromagnetic radiation to a fluid reservoir (11) arranged around the heating means (10) within the treatment catheter (12) and to surrounding bodily tissue and

emitting conductive heat from the fluid reservoir (11) to an area of the prostatic urethra and the prostate (19) between the apex of prostate and the bladder neck (21').

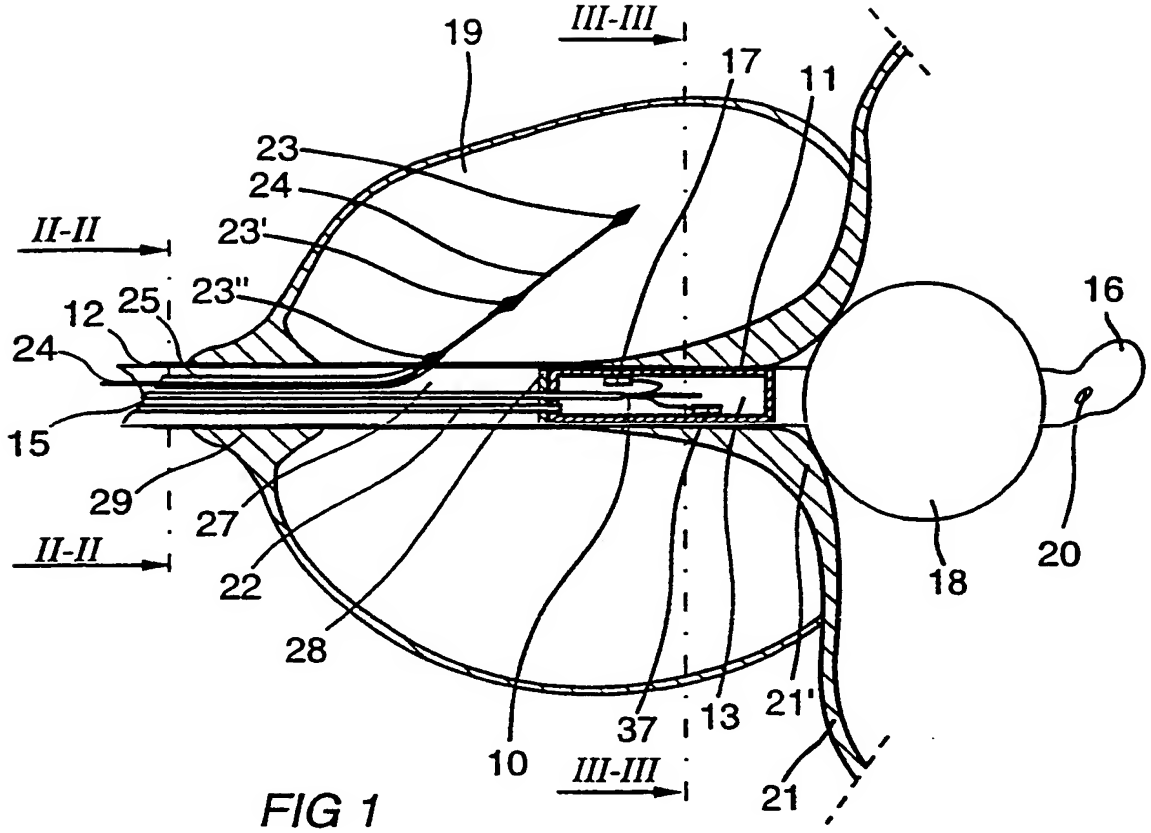

FIG 1

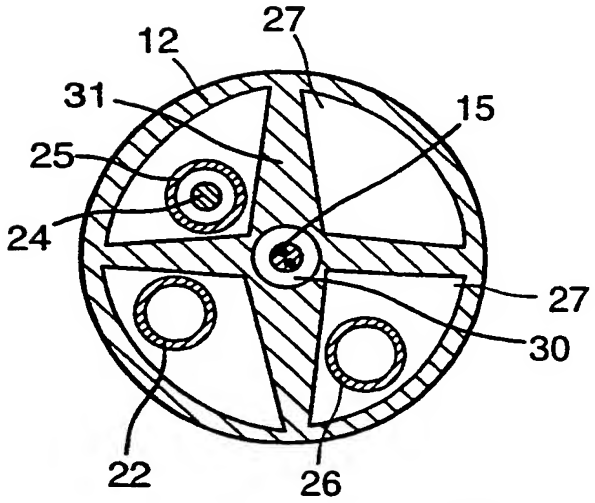

FIG 2

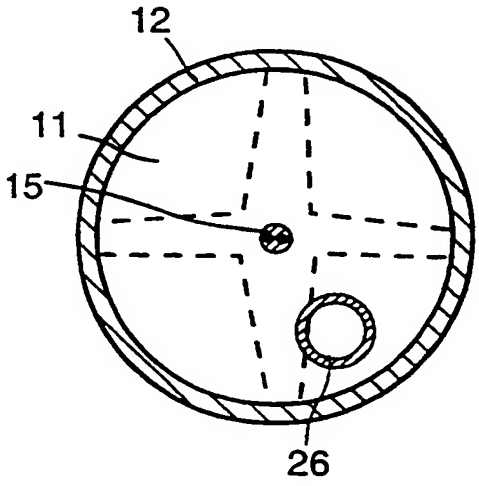

FIG 3

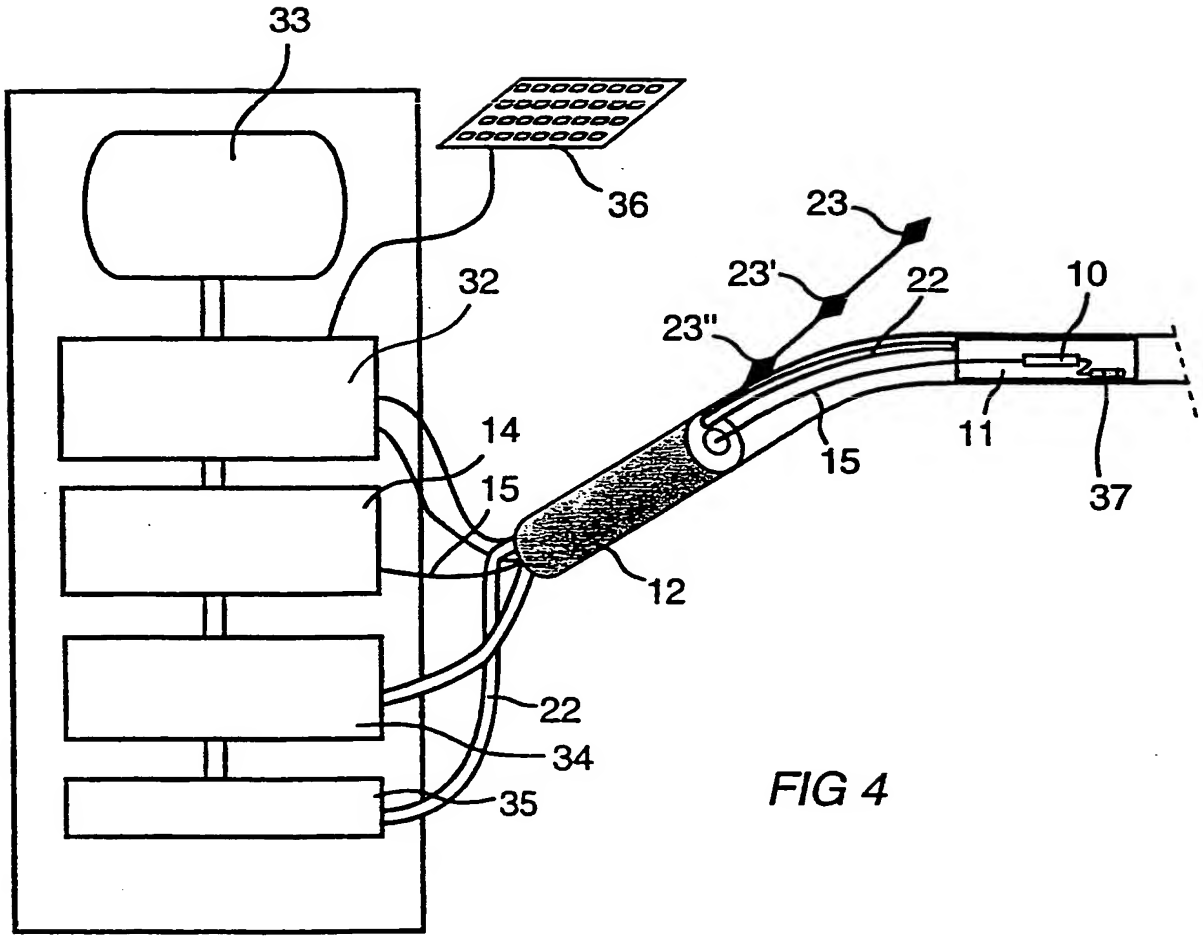

FIG 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00905

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 7/12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SE 9703608-1 A (LUND INSTRUMENTS AB), 3 April 1999 (03.04.99)	1-6
	--	
A	SE 507465 C2 (LUND INSTRUMENTS AB), 8 June 1998 (08.06.98), page 3, line 24 - line 30	1
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☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2000	04 -09- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Anette Hall/Els Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE00/00905

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 7
because they relate to subject matter not required to be searched by this Authority, namely:

See PCT Rule 39.1(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).:

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

08/05/00

International application No.
PCT/SE 00/00905

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
SE 9703608-1 A	03/04/99	NONE	
SE 507465 C2	08/06/98	AU 700815 B	14/01/99
		AU 6372296 A	10/02/97
		CA 2225561 A	30/01/97
		CN 1190340 A	12/08/98
		EP 0955969 A	17/11/99
		JP 11508798 T	03/08/99
		SE 9502523 A	08/01/97
		WO 9702794 A	30/01/97